REMARKS

Claims 1, 5-7, and 26-30 are pending in the application. Claims 1 and 5 have been amended. Support for the amendments can be found throughout the application and as indicated below. It is believed that no new matter has been added to the application.

In light of the amendments and discussion to follow, reconsideration and allowance of all of the pending claims is respectfully requested.

Priority

According to the Office Action, claims 1, 5-7, and 26-29 are not entitled to benefit of the earlier filing date of U.S. Provisional Application Serial No. 60/444,637 from which the present application claims priority.

According to the Office Action "...claims 1, 5-7, and 26-29 do not properly benefit under 35 U.S.C. §§ 119 and/or 120 by the earlier filing dates of the priority documents claimed, since those claims are rejected under 35 U.S.C. §112, first paragraph, as lacking sufficiently enabling disclosure." (See page 2 of the Office Action.)

Claim 1 has been amended to specifically recite a method of detecting a colon or lung cancer marker including detecting an expression profile of a nucleic acid in a colon or lung cancer tissue from a human subject and comparing the expression profile to the expression profile of the nucleic acid in a corresponding normal lung or colon tissue to determine whether the nucleic acid is overexpressed in the cancer tissue. The claims encompass nucleic acids as in SEQ ID NOs:1, 12, 26, and 31.

Support for claim 1, as amended, and its dependent claims, is found throughout U.S. Provisional Patent Application No. 60/444,637. For example, support is found at pages 16, lines 1 through 9; at page 38, lines 22 and 23; at page 30, lines 15 through 19; on Table 2, and in Example 1. More specifically, Example 1, at pages 106 and 107 of describe the methods used to identify the cancer-related protein kinases for use as cancer markers. The differential mRNA expression of the markers in the specific tumor specimens relative to the corresponding normal tissue, and the fact that the markers were found to be upregulated in cancer and lung cancer, is discussed at page 16, lines 1 through 9. Table 2 lists the SEQ ID NOs of the different

cDNA sequences including ATR as SEQ ID NO:1, CHEK1 as SEQ ID NO:12, NEK2 as SEQ ID NO:26, and PLK as SEQ ID NO:31.

Applicants respectfully submit that the priority document provides enabling disclosure for the claimed invention. Thus, the effective filing date of the subject matter being claimed is appropriately February 4, 2003. Accordingly, Applicants request the benefit of the filing date of U.S. Provisional Application Serial No. 60/444,637 from which the present application claims priority.

Grounds of Objection and Rejection Withdrawn

Applicants appreciate and acknowledge the Examiner's removal of the objections and rejections set forth in the Office Action mailed February 20, 2007.

Grounds of Objection Maintained

The objection to the specification due to the use of improperly marked trademarks was maintained. The specification has been amended to properly mark trademarks and to address small typographical errors. Accordingly, Applicants respectfully request reconsideration and withdrawal of the objection to the specification.

35 U.S.C. § 112, first paragraph rejections

Claims 1, 5-7, and 26-29 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking enablement for using the claimed processes.

According to the Office Action, the specification does enable the skilled artisan to detect overexpressed mRNAs in colon or lung tissues as colon or cancer markers by comparing an expression profile of said mRNAs in a corresponding cancer-free colon or lung tissue. However, the Office Action alleges that the skilled artisan can not predict whether any such comparison to a "normal tissue reference profile "...will identify a marker of colon or lung cancer..." (See page 7 of the Office Action.) The Office Action further alleges that "...the specification, as filed, is not deemed sufficient to enable the skilled artisan to use the claimed invention at the time the application was filed without undue and/or unreasonable experimentation." (See page 8 of the Office Action.)

Claims 1 and 5 have been amended to refer to reference expression profiles from corresponding normal lung or colon tissue. Support for these amendments is found throughout the specification as filed, for example at pages 9-11, 14,15, 18,19, 23, and 30-32.

In light of these amendments, Applicants request reconsideration and withdrawal of the rejection under 35 U.S.C § 112, first paragraph, for lack of enablement of claims 1, 5-7, and 26-29.

New Grounds of Objection

In the Office Action, claims 7 and 26 were objected under 37 C.F.R. § 1.75(c) as allegedly being of improper dependent form for failing to further limit the subject matter of a previous claim.

According to the Office Action, in claim 7 "the method of claim 1 is practiced by detecting an expression profile of at least one nucleic acid in a colon cancer tissue, as opposed to a lung cancer tissue, from a human subject having lung cancer...[and]...it is unclear how or whether the limitation recited in claim 7 further limits the subject matter of claim 1." (See page 8 of the Office Action.) The Office Action brings the same argument regarding claim 26.

Claim 1 has been amended to recite methods comprising detecting an expression profile of a nucleic acid in a colon or lung cancer tissue and comparing the expression profile to the expression profile in a corresponding normal lung or colon tissue.

Applicants respectfully submit that the amendments to claim 1 obviate the objections under 37 C.F.R. § 1.75(c). As such, reconsideration and withdrawal of the objections under 37 C.F.R. § 1.75(c) of claims 7 and 26 is respectfully requested.

35 U.S.C. § 112, second paragraph rejection

Claim 30 was rejected under 35 U.S.C. § 112, second paragraph, as being indefinite.

According to the Office Action, claim 30 is allegedly indefinite for lacking antecedent basis for SEQ ID NO:31".

Claim 1 has been amended to include SEQ ID NO:31. Support for this amendment is found throughout the application as filed. For Example, at paragraph 21 and Table 1 of the instant Application.

Applicants submit that the amendments to claim 1 obviate the rejection under 35 U.S.C. § 112, second paragraph. As such, reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, second paragraph, indefiniteness of claim 30 is respectfully requested.

35 U.S.C. § 102 (a)

Claims 1, 7, 26, and 29 were rejected under 35 U.S.C. § 102 (a) as allegedly being anticipated by PCT Publication No. WO03/025138 A2 (Afar), published March 27, 2003.

The claims are drawn to methods comprising detecting an expression profile of a nucleic acid including SEQ ID NO:26 in a colon or lung cancer tissue from a human subject and comparing the expression profile to the expression profile of a nucleic acid including SEQ ID NO:26 in a corresponding normal lung or colon tissue to determine whether the nucleic acid is overexpressed in the cancer tissue. According to the Examiner, "...Afar anticipates these claims." (See page 10 of the Office Action.)

As stated above, Applicants are entitled to the effective filing date of February 4, 2003, for the subject matter being claimed in the instant application. As such, a rejection under 35 U.S.C. § 102(a) rejection of claims 1, 7, 26, and 29 under Afar, which published March 2003, is improper. Accordingly, reconsideration and withdrawal of the rejections under 35 U.S.C. § 102(a) of claims 1, 7, 26, and 29 is respectfully requested.

35 U.S.C. § 103(a) rejections

Claims 1, 5, and 6 were rejected under 35 U.S.C. § 103(a) as allegedly being anticipated by Afar, published March 2003.

Claims 1, 5 and 6 are drawn to a method wherein the normal tissue reference profile is an average expression profile of the at least one nucleic acid and wherein the expression profiles are determined using RT-PCR or nucleic acid arrays. According to the Examiner, "...Afar et al. teach said expression profiles being determined using PCR or nucleic acid arrays...[and that] it would have been *prima facie* obvious to

determine the average value of the expression profiles..." (see pages 11 and 12 of the Office Action).

As stated above, Applicants are entitled to the effective filing date of February 4, 2003, for the subject matter being claimed in the instant application. As such, a rejection under Afar, which published March 2003, is improper. Accordingly, reconsideration and withdrawal of the rejections under 35 U.S.C. § 103(a) of claims 1, 5 and 6 is respectfully requested.

Claims 1, 5-7, 26 and 27 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No. 6,632,936 (Carr), in view of U.S. Patent No. 7,101,985 (Elledge), and U.S. Patent No. 6,709,832 (Von Knebel Doebertiz).

The claims are drawn to methods including detecting an expression profile of a nucleic acid including SEQ ID NO:1 in a colon or lung tissue sample from a human subject and comparing the expression profile to the expression profile of a nucleic acid including SEQ ID NO:1 from a corresponding normal colon or lung tissue to determine whether the nucleic acid is overexpressed in the cancer tissue. In dependent claims 5 and 6, the normal tissue reference expression profile is average expression profile and wherein the expression profiles are determined using RT-PCR or nucleic acid arrays.

According to the Office Action, Carr allegedly teaches methods of detecting an expression profile of an mRNA that encodes a cell cycle checkpoint polypeptide comprising SEQ ID NO:1 from lung or colon cancer tissues that is 99.7% identical to the instant SEQ ID NO:1. The Office Action also alleges that Carr teaches methods of detecting an expression profile of an mRNA that encodes a cell cycle checkpoint polypeptide from colon cancer tissues, and that Carr teaches that the expression profiles may be determined using RT-PCR or nucleic acid arrays (see page 13 of the Office Action). The Office Action cites Elledge as allegedly teaching an mRNA including a nucleotide sequence which encodes the same cell-cycle polypeptide as the polypeptide referred to by Carr, and that the nucleic acid sequence disclosed by Elledge is 100% identical to instant SEQ ID NO:1. (See paragraph bridging pages 13 and 14 of the Office Action). The Office Action cites Von Knebel Doebertiz as allegedly teaching "that it is an obvious thing to compare an mRNA expression profile from a cancerous body sample with a corresponding mRNA expression profile from a body sample which originates from a healthy person..." (see Office Action page 14).

As stated above, Applicants are entitled to the effective filing date of February 4, 2003, for the subject matter being claimed in the instant application.

Carr published March 1997 as PCT Publication No. WO97/09433, Elledge published September 4, 2003 as US Application No. 2003/0165934, and Von Knebel Doeberitz published January 2000 as PCT publication No. WO00/01845. Elledge published after the effective filing date of the instant Application and it is not a proper prior art reference under 35 U.S.C. § 103(a). Without Elledge, which teaches a nucleic acid 100% identical to SEQ ID NO:1, Carr and Von Knebel Doeberitz do not together teach or suggest all of the claimed elements. Accordingly, reconsideration and withdrawal of the rejections under 35 U.S.C. § 103(a) of claims 1, 5-7, 26 and 27 is respectfully requested.

Claims 1, 5-7, 26 and 28 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No. 7,081,340 (Baker), in view of U.S. Patent No. 6,709,832 (Von Knebel Doebertiz).

According to the Office Action, Baker teaches methods of detecting an expression profile of an mRNA from lung or colon cancer tissues that is 100% identical to the instant SEQ ID NO:12, and that the expression profiles are determined using RT-PCR or nucleic acid arrays (see page 17 of the Office Action). The Office Action cites Von Knebel Doebertiz as allegedly teaching "that it is an obvious thing to compare an mRNA expression profile from a cancerous body sample with a corresponding mRNA expression profile from a body sample which originates form a healthy person..." (see paragraph bridging pages 17 and 18 of the Office Action). The Office Action indicates that it would have been prima facie obvious "to determine the average value of the expression profiles of that nucleic acid in the samples using such methodology." (See page 19 of the Office Action).

As stated above, Applicants are entitled to the effective filing date of February 4, 2003, for the subject matter being claimed in the instant application. As such, a rejection under 35 U.S.C. § 103(a) under Baker, which published December 4, 2003 is not proper because it published after the effective filing date of the instant application. Without Baker, which according to the Office Action, teaches methods of detecting an expression profile of an mRNA from lung or colon cancer tissues that is 100% identical

to the instant SEQ ID NO:12, and teaches the expression profiles being determined using RT-PCR or nucleic acid arrays, Von Knebel Doeberitz does not teach or suggest all of the claimed elements.

Accordingly, reconsideration and withdrawal of the rejections under 35 U.S.C. § 103(a) of claims 1, 5-7, 26 and 28 is respectfully requested.

CONCLUSION

In view of the above amendments and remarks, Applicants respectfully assert that the Application is in form of allowance. As such, allowance of the amended claims is respectfully requested.

A petition and authorization to charge the fee for a one (1) month extension of time accompanies this response. During the pendency of this application please treat any reply requiring a petition for extension of time for its timely submission as containing a request therefore for the appropriate length of time. The Commissioner is hereby authorized to charge all required extension of time fees during the entire pendency of this application to Deposit Account No. 01-1425.

If any outstanding issue remains, the Examiner is invited to contact the undersigned agent for a discussion of a mutually agreeable solution.

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